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HALOGENATED SOLVENTS INDUSTRY ALLIANCE, INC.

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June 24, 2004

Certified Mail - Return Receipt Requested

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Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
US Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

2004 JUL -9 PM 2:29

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Re: Trichloroethylene (CAS Number 79-01-6)

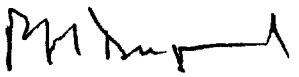
Dear Sir or Madam:

This letter is to inform the Environmental Protection Agency (EPA) of certain preliminary findings from an inhalation immunotoxicity study in rats employing the above test material. The Halogenated Solvents Industry Alliance, Inc. (HSIA) is making this submission on behalf of the sponsors of the study (The Dow Chemical Company, INEOS Chlor Americas, PPG Industries Inc.). The study is part of HSIA's voluntary program to assist the Agency for Toxic Substances and Disease Registry to fill "priority data needs" and is also part of HSIA's commitment to EPA's Voluntary Children's Chemical Evaluation Program (VCCEP).

Groups of 8 female CD rats were exposed to atmospheres of trichloroethylene of 0, 100, 300 or 1,000 ppm for 6 hours/day, 5 days/week for 4 weeks. Immunotoxicity was assessed in accord with EPA Guideline OPPTS 870.7800. In order to evaluate the functional response of the immune system, rats were immunized with sheep red blood cells (SRBC, a T-cell dependent antigen) 4 days before the end of the exposure period. The antibody, plaque forming cell (AFC) assay was performed within 24 hours of the last exposure to determine effects on splenic anti-SRBC IgM response. Preliminary results for rats in the 1,000 ppm top dose group indicate a reduction in the AFC response after normalization for the number of splenocytes. The value for AFC/10^6 splenocytes was 385 ± 260 in top dose animals versus 1082 ± 473 in controls, representing a reduction in the mean of 64.4% for treated animals. Full statistical evaluations have not been completed but no reduction in AFC/10^6 splenocytes was apparent in rats in the 300 or 100 ppm dose groups, and no effect on spleen weight was discernible at any dose level. Results of histopathology of the spleen are not yet available. Qualitatively similar reductions in responses to SRBC have been seen previously in female CD-1 mice exposed for 4 months to 2.5 and 5 mg/ml of trichloroethylene in drinking water (Sanders *et al.*, 1982).

Under current guidance issued by EPA regarding Section 8(e) of the Toxic Substances Control Act, it is our understanding that the results for the SRBC assay in the rat inhalation study are reportable despite similar effects having been observed in a mouse drinking water study. HSIA has made no determination as to whether the results indicate a substantial risk to humans whose exposures are equivalent to much lower levels than the present 300 ppm NOAEL for the SRBC assay.

Sincerely,



Paul H. Dugard, PhD
Director of Scientific Programs